UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 6

AUDIT SUMMARY - OVERALL PROGRAM RATING	
Nestlé Audit Workbook (Contract Manufacturers and Cofillers)	
Audit Date:	July 25 - 27, 2022
Site Name:	creative werks - Bensenville, Brummel, and Bartlett, IL
Overall Audit Rating	
Satisfactory/Approved	

AUDIT SUMMARY - OVERALL PROGRAM RATINGS		
Compliant	**Critical**	**Major**
13	0	4
Minor	**Continuous Improvement**	**Not Audited / Not Applicable**
1	1	1

Program	Rating
HACCP	Major
Thermal Processing	Not Applicable
Microbiology	Compliant
Allergen Management	Major
Cleaning & Disinfection	Compliant
FM Control	Compliant
FM Control Glass	Compliant
Supplier	Compliant
Raw, Pack & Finished Prod	Major
Net Contents	Minor
Sensory	Compliant
Traceability	Compliant
Recall & Withdrawal	Compliant
Non Conform & Change Mgmt	Major
Disposal & Destruction	Compliant
Water Quality & Safety	Compliant
Pest Management	Continuous Improvement
GMP	Compliant
GMP Inspection	Compliant
Management Commitment	Compliant

TOTAL GAP COUNT SUMMARY	
Audit Gap Count (includes GMP Inspection)	***# Findings***
Minor	18
Major	13
Critical	0
Total	***31***

SCORING DEFINITIONS & IMPACT

Individual Program(s) & Requirement Ratings		
Risk	**Definition**	**Recommended Period for Corrective Action Closure**
Critical	There is a CRITICAL risk to food safety or regulatory compliance. The item / area / system observed has a CRITICAL design flaw, weakness in implementation or control. Key controls are absent or inadequate. Quality Leadership must be contacted.	30 days
Major	The item / area / system observed has a MAJOR design flaw, weakness: implementation, control, multiple deviations observed in execution or documentation. Planning and prioritization for closure must be agreed upon by Quality Expert.	3 months
Minor	The item / area / system observed has a deficiency that does not meet the MAJOR definition, but requires corrective action. Gaps should be closed according to recommended period for corrective action.	6 months
Continuous Improvement	No deficiency observed, but there is an opportunity for improvement.	optional

Overall Audit Assessment & Business Impact			
Overall Rating	**Rating Description**	**Business Strategy**	**Contract Manufacturer Status**
Good	The audit results include no issues, which would be considered significant.	Continue to conduct business as usual	Approved
Satisfactory	The audit results identified a few issues in need of attention, but none shows significant or fundamental weaknesses in controls, compliance and/or operations.	Continue to conduct business as usual and close gaps.	
Not entirely satisfactory	The audit results identified a number of issues in need of prompt attention to correct a significant control, compliance or operational problem and/or some issues from previous audits have not been corrected in a satisfactory manner.	No new volume, no discussion of new products, must revisit strategy at some pre-determined interval	
Unsatisfactory	The audit results identified a large number of issues and/or significant issues and/or serious issues from previous audits, which have not been corrected in a satisfactory manner. Certain key controls are absent or inadequate and generate significant risk to the company.	Must consider exit or movement of volume to another facility	Not Approved

Nestlé
Good Food, Good Life

Issue Date: January 31, 2022
Annex 1-2, Version: 1

CoManufacturers and Cofillers Audit

Audit Date:	**July 25 - 27, 2022**
Site Name:	creative werks - Bensenville, Brummel, and Bartlett, IL
Site Manager:	Doug Mauger, VP Operations & Engineering (for all 3 sites)
Quality Manager:	Erich Zicher, Director of Food Safety
Other Site Representatives:	Angela Knabe, Matt Burke, Luis (Maint), Jamas Pugh, Silvana Perez, Martin Garcia, Javier Flores, Dider Mijangos, Scott Nelson, Tony Grandinetti, Brian Phillips
Nestle Audit Team Members:	Donna Bjurlin, Susan Edmondson
Report Sent To:	Angela Knabe, Erich Zicher, Susan Edmondson

Contact Information

Facility Type:	Cofiller	
Address:	1) 222 Sivert Court, Bensenville, IL 2) 1470 Brummel Avenue, Elk Grove Village, IL 3) 1350 Munger Road, Bartlett, IL 60103	
Phone:	(630) 509-3087 - Erich Zicher	
Facility Size / Age:	Bensenville - built in 1977, occupied 1999 Brummel - built in 1977, occupied 2013 Bartlett - built 2006, occupied 2015	Bensenville - ~187,000 sq. ft. Brummel - ~242,000 sq. ft. Bartlett - ~400,000 sf ft
Number of Employees:	~ 237 employees, with 300 - 1500 temporary employees, depending on seasonality	
Number of Production Lines:	Bensenville - 21 Brummel - 16 Bartlett - 28, not including winding (6) & blow molding (6)	
GFSI 3rd Party Certification / Current Rating:	SQF Food Safety Code for Manufacturing & SQF Quality Code	96 Excellent (FS) Certified (Quality)
FDA Registration # / USDA Registration #:	Last 4 digits: BEN - 1646 BRU - 6638 BAR - 0478	N/A
Nestle Business/Category(ies):	Bakery Sweets	

Products Manufactured for Nestle

Co-filling of Morsels (currently Milk & Funfetti), Morsels & More (multiple flavors), Truffles (multiple flavors)

Additional Scope / Background Information

Currently no Nestlé volume in the Bartlett factory, however the site was included in the audit to allow site to continue to be an option.

Overall Audit Rating

Satisfactory/Approved

Executive Summary

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
HACCP	All Nestlé products and their components, including raw materials, packaging materials and process aids, are considered in a HACCP study. All processing steps and movement are considered in the HACCP study.	The Ingredient Risk Assessment document lists potential hazards for high-level ingredient/WIP groups (e.g. chocolate with inclusions, chocolate, or nuts) however no risk assessment (evaluating severity / likelihood) is performed. Risk Assessment documented conclusion (See Auditor Notes) does not negate the site's responsibility to evaluate the risks of the site's incoming materials. The current grouping of ingredients will not adequately support a proper risk assessment of incoming materials Same finding for packaging and process.	Major	One Food Safety Plan for packaging (across all three factories), one for coffee, one for Tubes and Toppers Documented conclusion reached on ingredient hazards in the Ingredient Risk Assessment states, "Client... have instituted policies around Biological and Chemical concerns with their food manufacturers which we verify through our Auto hold / CofA process"	1	Food safety plans will be re-written to included severity and likelihood. Food safety plans will be re-drafted to include the hazard analysis within - not as a separate document. Packaging and process will also be included.	Angie	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
HACCP	An annual review of the HACCP study must take place and all updates must be captured.	Ingredient Risk Assessment changes are not included in the annual reviewed and no change control associated	Major	11/4/21 Pkg Food Safety Plan	2	Since the risk assessment will be embedded within the food safety plan, it will become part of the annual review. New change control froms will include a review of the food safety plan for new processes or products.	Angie	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
Microbiology	The relevant pathogen(s) as well as the associated hygiene indicator(s) has been identified.	Relevant [redacted] tested (e.[redacted])	Minor	Target organisms are Listeria spp and Salmonella; Currently uses hygiene indicators only to show effectiveness of cleaning (validations)	3	Will review the program and how best to address	Erich	31-Mar-23		

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Microbiology	The site Hygienic Zoning program was developed using a risk based analysis.	Sanitation Rooms miscategorized as BGMPs in some documents	Minor	Facility Zoning & Workflow WI-3.1 v10 - dated 2022-01-31 splits facility into 3 zones (non-mfg, BGMPs (all GMPs/partial attire), and PPCA (all GMPs/attire)) Developed based on risk - production environments and the traffic flows around that; Certain areas forktrucks are not allowed due to allergen risks, for example BEN uses Sterliex for forktruck wheels	4	Identifying colors will need to be updated to correctly reflect the zoning.	Angie	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence
Microbiology	The site zoning plan must be supported by verification plan with defined verification activities.	The site zoning plan does not appear to be supported by verification plan with defined verification activities. (WI 3.1 also requires annual verification)	Minor	Facility Zoning & Workflow WI-3.1 v10 - dated 2022-01-31 requires Annual Verification in conjunction with the Pkg FS Plan review	5	WI does require annual verification - will need to update to define what those verification activities are .	Angie/Erich	18-Apr-23	Closed	Brittany Pace - Review of submitted evidence

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[redacted] nt	A MAD form or equivalent local [redacted] raw materials and finished products.	A sample review of the Nestlé Finished Product MAD forms (when compared against the site's ERP [redacted] some MAD forms are incorrect. (e.g. [redacted] pack configurations) Nestlé gap: MAD form for incoming material (NTH White Morsel) is out of date)	Minor	MAD forms exist for all active finished good SKUs (confirmed updated within last 3 years) MAD for [redacted] dicates treenut as allergen in product (highly refined coconut) - but not in ERP setup / labeled on packaging (suspect error) (also not listed in the different ingredients' MAD) NTH White morsel MAD is out of date (Bloomington source)	6	•M&M Peppermint Hot Cocoa – bag has allergens listed as milk & soy, however MAD form dated 3/30/21 (attached) indicates treenut allergen coming from highly refined coconut oil. [redacted] MAD form for accuracy and advise if update is needed / where coconut oil comes from •NTH Premier White Morsel (ingredient) – MAD and Kosher documentation are from obsolete supplier site (Nestle Bloomington) oSusan (by 9/16) – get updated documentation from current supplier site (Nestle Burlington)	[redacted] CW CW Susan	[redacted] 10/1 10/1 11/1	Closed	D. [redacted] Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Allergen Management	Is there an Allergen matrix in place	[redacted] clarity to all involved which lines may run which allergens (based on cleaning [redacted] Currently if a change to a line is made, only quality is aware and it on the Quality personnel to attend every Scheduling meetings to prevent Scheduling from selecting a line that is not current on cleaning validations/verifications or allowed to run that allergen at the moment. (See Auditor Notes for additional context)	Major	Changeover matrix available that specifies all allergens from/to and sanitation requirements. Not product specific info. ERP setups specify the full allergen profile of each item being running. Reviewed SPC1 Line Clearance & Full sanitation Cleaning Checklist after completing NTH Kitchen Sink product (dairy/soy/wheat) to soy/wheat product from Apr'22. Allergen cleaning - full was completed and verified. There is a software that runs a report showing the allergens ran on a line based on the timeline entered. On the line (Ln 380) reviewed, we found that if we looked back to 2021, peanut was listed and when we selected today's date, it is not listed. The line is past due for allergen cleaning verifications. It was stated that they are not allowed to run peanut on the line currently, however when the QAM asked Scheduling of this	7	Matrix will be developed detailing which allergens/clients are approved to run on each of the production lines	Angie	12/31/2022 - realizing this timeline does not meet the deadline for a Major - however, this will restructure how we plan and execute production. More time will be required.	Closed	D. Bjurlin - Review of submitted evidence

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Allergen Management	Are annual verifications in place?	(Repeat finding) Bensenville could not produce evidence of annual verifications on Ln 380 (and there is no control method to prevent scheduling from running peanut on the line as mentioned above)	Major	BRU - Allergen annual verification on Ln1300 performed 4/18/22, Ln 2400 performed 5/2/22; BEN - the evidence could not initially be located and the QA personnel were on vacation - evidence was found for Ln 200 - 3/31/22; Ln 250 - 8/6 & 8/20/21; Ln 380 - 5/21/21 was the last one performed; See above auditor notes for more context	8	Will audit to determine why we are behind in validations at Ben. Michaela to propose action plan based on schedule.	Angie/Michaela	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence
FM Control	• Equipment under repair/re-construction/maintenance must be inspected, relating to FB, before being cleared for release.	No evidence could be provided to demonstrate equipment under repair/re-construction/maintenance is inspected (relating to FB or micro) before being cleared for release	Minor	assessing as minor due no processing equipment, the # of FM complaints received, and the overall condition of the facility	9	Need to meet with Maintenance and Sanitation to understand the worfklow for items needing maintenance and how those items are then cleared for use in production.	Brian Phillips/Michael Glowa/Angie	1-Jan-23	Closed	D. Bjurlin - Review of submitted evidence
FM Control	Temporary repairs using inappropriate auxiliary materials such as tape, must be avoided. If temporary repairs are used, there must be a policy which includes finite period of time allowed with proper repair scheduled.	There is no mention of an allowed period of time for proper repairs to be scheduled for temporary repairs.	Minor	Generally not allowed unless waiting on a part, etc, however this was a verbal expectation	10	WI for temporary repairs will be updated with the time and materials allowed for temporary repairs	Angie	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence

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Raw, Pack & Finished Prod	Materials received from unapproved vendors trigger the exception management process and documented	In general, approving release for incoming materials from unapproved vendors currently does not include involving Nestlé. Additionally, during a spot check, an example of (Funfetti) film on auto hold was found to come from [redacted] however, the approved supplier (in Ch 5) is Story City, IA. It did not trigger the ER process and was released internally. (We didn't continue to spot check)	Minor	Since it is the Ship From site that triggers the ERP system to auto-hold, it takes extra manual confirmation by Angie to review if the receipt is from a truly unapproved vendor site or not; We reviewed some examples; Typically the issue is the ship from site is a warehouse, and we can see on the paperwork that the manufacturing location is truly the approved site; We aligned that if this wasn't the case, an ER submitted to Nestle would be required for release moving forward. Is there a strong enough tie between the Approved Supplier list in Chapter 5 and the Supplier approval process at CW?	11	Approved cw vendors for Nestle will be verified against the list of approved vendors in Chapter 5. If the shipping paperwork identifies a location other than what is on the approved list, an ER will be submitted to Nestle.	Angie	31-Mar-23	Closed	D. Bjurlin - Review of submitted evidence

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Raw, Pack & Finished Prod	Information to support the release decision such as sampling, inspection and analytical data must be recorded and traceable by factories.	Incoming receipt COA review is not consistently requiring the full list of required parameters per the Ch 5 specification or the COA comparison table, when available). Example: 6/2/22 Dulce de Leche truffle receipt COA was missing 3 of the 6 micro parameters listed in the spec (included: Eb, S, TPC; missing: YAM, coliforms, and E.coli) (no further spot check performed) The check of the Seal # matching the BOL is not documented.	Major		12	Will review chapter to 5 to determine the micro parameters and then follow up with our suppliers to ensure they are conducting the required tests. Any push back from the suppliers will be escalated to Nestle Quality	Angie	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
Raw, Pack & Finished Prod	The factory is responsible for identifying the release characteristics through the Factory QMS or equivalent. They correspond to: a. Critical Control Points (CCP); b. Operational Pre-Requisite Programs (OPRP); c. Control Points (CP); d. Monitoring inspections (M1) covering contaminants & regulatory requirements (not measured on each batch).	The site's release characteristics are not 100% aligned with the pQMS and/or MI's (Manufacturing Instructions) listed in Chapter 5 (ex: M&M pQMS with regard of level of criticality)	Major	Qwerks is where release characteristics are listed; The FSP is where the SPC and PCPs are denoted	13	Need to review the pQMS to ensure they align with the information contained within the MIs. Once that has been confirmed as aligning, the information in the Mis needs to align with the release criteria listed in Qwerks.	Amanda/Matt/Michaela	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence

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Raw, Pack & Finished Prod	The use of rework is defined by Nestle Technical Applications. Rework is traced and accounted for.	(Nestlé Gap) The use of rework is not defined in Chapter 5	Minor	WI 3.10 Rework requires for multi component that they either separate out the individual components and rework or use a separate scale and manage it to where the ratios are still met. Rework has to be done on the same shift, unless the rework is a result of a hold.	14	CAR#14: I recall the gap identified here around re-processing, not full fledged rework where a new batch# is assigned. Can you confirm? (Maybe question is to @Bjurlin,Donna,US-Solon) If that's the case proposed action: •CW team (by 10/1) – advise if rework (with new batch # assigned) is a process @ CW, and of so share •CW team (by 10/1) – share any policies around online re-processing •Susan (by 11/1) – Draft rework & re-processing requirements from Nestle with alignment from TAG for current portfolio.	CW CW Susan	10/1 10/1 11/1	Closed	D. Bjurlin - Review of submitted evidence

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Raw, Pack & Finished Prod	Release must be done by: a. The Contract Manufacturer according to mutually agreed standards and rules with Nestlé operating companies, or b. Performed by the Nestlé operating companies	Finished product testing / release is not aligned with the criteria listed in the Chapter 5 (examples found: [redacted]ratios OOS from 6/23 and released, missing end of runs checks in general, line clearance documentation review is not part of release process	Major	Unapproved vendor finding will be addressed in the finding above and not-double dipped here (Line clearance review done earlier in process by other personnel, however there should be some connection that the paperwork is available and complete.	15	Will need to review QMS release parameters with the Food Safety and Quality Managers for each site. Will need to determine if another review of the line clearance sheet needs to be apart of the release process.	Quality Management	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
Net Contents	Product intended for US only: 50% or more of individual packages must be greater than declared label net contents (E) as statistically calculated	The Net Content Compliance WI WI-2.18 does not align with this requirement. The WI states "no more than 30% of the actual samples can fall between Label and MAV" Mathematically, this does not guarantee 50% statistically calculated.	Minor		16	Review of Net Contents WI and practices to ensure the mean value of the population is greater than the declared label weight. Adjustments to WI will be made based upon assessment.	Marcus Willamson	1-Feb-23	Closed	D. Bjurlin - Review of submitted evidence

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Net Contents	Product intended for US only: With Checkweigher, no packed units below an absolute lower limit - No packed units below an absolute limit (MAV). Note (not auditable): Refer to US tab in R3.16.3 Lot Review Selectable Limits USDA MAV Table 2-9 FDA labelled by weight MAV Table 2-5 FDA labeled by count Table 2-7 FDA labeled by liquid or dry volume table 2-6	Found evidence of a production run with MAVs that was being released by site. (Found hold product due to MAVs during factory walkthrough. Internal notes stated "Pallet would be released as the entire lot met spec". No one from Nestle had been informed - M&M, Production date - 7/20/22)	Minor	MAV samples created and ran across checkweigher bihourly 3 times;	17	If finished good failed to meet MAV, this would follow an escalation and ER process which would include Donna to align on next steps.	Matt/Michaela	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence
Net Contents	Product intended for US only: The tare is determined at the beginning of every production is recorded and used for all scale tares.	Tare is not recorded. Tare Variability Study for all products could not be produced per the Net Content Compliance WI WI-2.18, section 5.3.1	Minor	Spot check: the Morsels & More Tare Variability study could not be located	18	Will audit current cw projects running for Nestle to ensure a tare variability study has been conducted and is on file	Matt/Michaela	15-Feb-23	Closed	D. Bjurlin - Review of submitted evidence
Recall & Withdrawal	An after-action review must be conducted when the crisis is over and potential improvements implemented. As a minimum, an analysis of the involved quantities of finished products must be made (produced, sold, returned, destroyed and not accounted for or consumed).	After action review not conducted	Minor	Analysis of quantities accounted for	19	Results of any mock trace or mock recall will be included in the next month's Food Safety team meeting.	Angie	13-Sep-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Non Conform & Change Mgmt	Assess if the deviation leads to material rejection (or if the blocked batches may be exceptionally released or unblocked). Release decision is owned by Nestle Quality.	Release decision for non-conformities is not consistently being brought to Nestlé Quality to own	Major	Discovered two situations where product was held and released by Creative Werks in July without communication to Nestlé. Both were for net content. Other spot check - reviewed peanuts that just went on expiry and were on hold pending review	20	Any Nestle product that is put on hold will be communicated to Nestle Quality to align with disposition. Training from Matt and Michaela to follow.	Matt/Michaela	26-Sep-22	Closed	D. Bjurlin - Review of submitted evidence
Non Conform & Change Mgmt	Check if the same material and/or material batch is (or has been) used in other products and assess the impact accordingly.	Checking to see if the same material and/or material batch is (or has been) used in other products when there is a hold is not documented in the procedure.	Minor	Trace - would run a raw material report to review where used. If any product produced with sublot - automatically put on hold, but if shipped out already - would notify customers. All additional inventory would go on hold.	21	Will update procedure to clearly identify what happens then material from a certain lot goes on hold.	Angie	1-Dec-22	Closed	D. Bjurlin - Review of submitted evidence
Non Conform & Change Mgmt	Each result which is out of the Factory QMS or equivalent limit(s) for a release characteristic must trigger a Root Cause Analysis (RCA) investigation that leads to corrective action(s) avoiding the re-occurrence of the failed result.	Could not provide evidence of consistent root cause / corrective action on all Nestlé product holds consistent with WI and this Nestlé requirement.	Minor	WI-2.7 Corrective Action / Preventative Actions (CAPA) Rev 7, dated 4/17/20 Verbal answer - Per client request will conduct RCA & CAPA. Have internal CAPAs based on trending gap data. No recent CAPAs completed on Nestle items. WI is more black/white on when it is needed vs per client request	22	As part of communicating with Nestle on all holds to align on dispositon, it should be communicated whether Nestle will reuqire an RCA and CAPA on the specific hold.	Matt/Michaela	26-Sep-22	Closed	D. Bjurlin - Review of submitted evidence

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Non Conform & Change Mgmt	The Contract Manufacturer must have a Management of Change process in place to manage changes to products, processes, equipment & workplaces that affect HACCP program, product quality, food safety, regulatory compliance, (e.g.: change on the label).	Insufficient/ineffective MOC process in place. Site could not provide evidence of MOC execution for internally-initiated changes, nor could show proper execution of client-initiated changes.	Major	Examples: M&M ingredient extension MOC dated 1/3/22 NTH Generic Release Instructions 6/29/22, Change in graphics/item formulation gets communicated from client services email and triggers a review. Would get reviewed due to the primary packaging review to assess any allergen updates needed based on change; Unclear how this ties into the change control process. Ingredients - reviewed a FST meeting minutes 7/13/22 where it showed a list of new materials	23	Management of Change program will be rewritten to include a new change control form.	Erich/Angie	3-Mar-23	Closed	D. Bjurlin - Review of submitted evidence
Pest Management	Nestle approved pesticide list is available and communicated to the Site IPM Champions and to the pest contractors	No letter of conformance available from [redacted] acknowledging receipt and adherence to the Nestlé approved Pesticide list	Minor	CW team has shared the current approved pesticide list with Rentokill for review, but verification has not yet been completed. List of Rentokill pesticides used is available in portal	24	Need to confirm Rentokil has uploaded the most current version of the APL.	Angie	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence

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GMP	A preventative maintenance program is in place for all process equipment that includes record-keeping and verification that work is completed. Maintenance request which impact Product Safety are given priority and on a timeline.	It was not evident during the audit that that Maintenance requests that impact Product Safety are given priority and on a timeline.	Minor	PMs are created when equipment comes in the building; PMs are assigned in ManagerPlus (M Plus); Oldest overdue is from 7/2/22, so appears the sites are staying up on PMs well overall; Run PM completion report weekly; Maintenance work requests are prioritized based on the priority of the line at the time;	25	Severity of repair has been identified in a Departmental Practice for the maintenance departments. Will need to update document to include an appropriate timeframe for each of the categories (Minor, Normal, Major, Critical)	Brian Phillips	1-Feb-23	Closed	D. Bjurlin - Review of submitted evidence

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GMP	Following major maintenance, work areas are inspected and released for production, with sign-off by the individuals responsible for the inspection.	At the time of the audit, the site could not provide evidence that following major maintenance, work areas are inspected and released for production, with sign-off by the individuals responsible for the inspection (neither in the way of written (or unwritten) procedure nor documented evidence)	Minor	In the workorder system, the maintenance staff will denote a food contact surface was handled and that will send an email notification to QA; It is unclear what happens after the receipt of that email, even by QA; The work order does not have a check box to denote the line has been released back to production. assessing as minor due no processing equipment, the # of FM complaints received, and the overall condition of the facility	26	Need to meet with Maintenance and Sanitation to understand the worfklow for items needing maintenance and how those items are then cleared for use in production.	Brian Phillips/Michael Glowa/Angie	1-Jan-23	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN & BAR - Warehouse	REPEAT FINDING: Insufficient programs in place to ensure dock doors and the use of said dock doors do not pose quality / food safety risks. Examples: BAR: 9+ dock door seals (drop curtains, wear pleats, etc) are in disrepair BEN - Door 11 had a missing window and the leveler was broken; Door 8 was missing dock leveler brushes; Door 7 leveler brushes deteriorated; Door 10 was left open 2 inches; BRU - Door 6 & others nearby - water ingress when raining; Evidence of air gaps observed in some cases when trailers are backed to the door (These were originally marked as BEN, however realized error and corrected on 2023-01-06)	Major	BAR Dock doors 23 (repeat), 28, 51 (repeat) None of these doors were being used at the time, therefore estimating risk/impact; Two of the three at BAR are repeat findings from last year Many doors were in use and did not allocate resource to evaluate each door at the time of the audit, and as such, there may be additional doors needing attention - suggest comprehensive assessment be performed BRU Warehouse overall looked great and showed nice improvement from last year. Nice work Scott and team! New or updated procedures, training, auditing, and trending required with appropriate management commitment required to address these findings successfully When implement updates	27	Monthly audits and proposed action with timeline will be reviewed and approved through senior leadership.	Warehouse management	17-Mar-23	Closed	D. Bjurlin - Review of submitted evidence
GMP Inspection	BEN - Warehouse	BEN - poor housekeeping especially around dock doors, inside and out, inclusive of excess wood splinters, trash on ground, and items stored in inappropriate locations	Minor		28	Housekeeping schedules will need to be reviewed to ensure areas are free of trash, debris, and wood splinters.	Tony Grandinetti	1-Jan-23	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN - Maintenance Shop	REPEAT FINDING (from sister site): FOB risks are not adequately managed / mitigated in BEN Maintenance shop and tracked to entrance of shop Examples: Metal shavings, bolts, nuts, etc found in multiple areas of the floor and cleaning broom FILLED with shavings; No vacuum near appropriate points of use;	Major	BAR Maintenance shop showed significant improvement, had vacuum near the source of contamination, floor was overall clean, chemicals locked, etc. Luis joined us for the tour (2nd shift) and was very engaged and appreciative of any feedback provided. Good work. BRU Maintenance shop processes still considered Best Practice (Nice work Dave and team); Two associates joined us and clearly articulated their procedures to clean immediately after their work and before going out on the floor, inclusive of their uniforms	29	Ben Maintenance will develop an action plan to ensure FOB are not able to leave the maintenance area. Weekly audit of the area to ensure action plan is working.	Jose Lopez	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN	On Ln250, scale door seals cracked and not appropriately attached to the door, creating potential FOB and micro risks	Major		30	Maintenance manager will review LN250 and submit his recommendation for needed repairs.	Jose Lopez	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence (Upon review, the gap was really with Ln 200)

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN	The method used to cover clean equipment is creating foreign body risks (2 or more pieces of clear plastic torn off of the plastic used to cover equipment after cleaning was found on the scale mezzanine and the steps to the mezzanine.	Major		31	Sanitation will review process for covering and uncovering equipment to determine if a different material or process is needed.	Michael Glowa	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence (Upon review, the gap was really with Ln 200)

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 7

AUDIT SUMMARY - OVERALL PROGRAM RATING	
Nestlé Audit Workbook (Contract Manufacturers and Cofillers)	
Audit Date:	July 25 - 27, 2022
Site Name:	creative werks - Bensenville, Brummel, and Bartlett, IL
Overall Audit Rating	
Satisfactory/Approved	

AUDIT SUMMARY - OVERALL PROGRAM RATINGS		
Compliant	Critical	Major
13	0	4
Minor	Continuous Improvement	Not Audited / Not Applicable
1	1	1

Program	Rating
HACCP	Major
Thermal Processing	Not Applicable
Microbiology	Compliant
Allergen Management	Major
Cleaning & Disinfection	Compliant
FM Control	Compliant
FM Control Glass	Compliant
Supplier	Compliant
Raw, Pack & Finished Prod	Major
Net Contents	Minor
Sensory	Compliant
Traceability	Compliant
Recall & Withdrawal	Compliant
Non Conform & Change Mgmt	Major
Disposal & Destruction	Compliant
Water Quality & Safety	Compliant
Pest Management	Continuous Improvement
GMP	Compliant
GMP Inspection	Compliant
Management Commitment	Compliant

TOTAL GAP COUNT SUMMARY	
Audit Gap Count (includes GMP Inspection)	***# Findings***
Minor	18
Major	13
Critical	0
Total	***31***

SCORING DEFINITIONS & IMPACT

Individual Program(s) & Requirement Ratings		
Risk	**Definition**	**Recommended Period for Corrective Action Closure**
Critical	There is a CRITICAL risk to food safety or regulatory compliance. The item / area / system observed has a CRITICAL design flaw, weakness in implementation or control. Key controls are absent or inadequate. Quality Leadership must be contacted.	30 days
Major	The item / area / system observed has a MAJOR design flaw, weakness: implementation, control, multiple deviations observed in execution or documentation. Planning and prioritization for closure must be agreed upon by Quality Expert.	3 months
Minor	The item / area / system observed has a deficiency that does not meet the MAJOR definition, but requires corrective action. Gaps should be closed according to recommended period for corrective action.	6 months
Continuous Improvement	No deficiency observed, but there is an opportunity for improvement.	optional

Overall Audit Assessment & Business Impact			
Overall Rating	**Rating Description**	**Business Strategy**	**Contract Manufacturer Status**
Good	The audit results include no issues, which would be considered significant.	Continue to conduct business as usual	Approved
Satisfactory	The audit results identified a few issues in need of attention, but none shows significant or fundamental weaknesses in controls, compliance and/or operations.	Continue to conduct business as usual and close gaps.	
Not entirely satisfactory	The audit results identified a number of issues in need of prompt attention to correct a significant control, compliance or operational problem and/or some issues from previous audits have not been corrected in a satisfactory manner.	No new volume, no discussion of new products, must revisit strategy at some pre-determined interval	
Unsatisfactory	The audit results identified a large number of issues and/or significant issues and/or serious issues from previous audits, which have not been corrected in a satisfactory manner. Certain key controls are absent or inadequate and generate significant risk to the company.	Must consider exit or movement of volume to another facility	Not Approved

Nestlé
Good Food, Good Life

Issue Date: January 31, 2022
Annex 1-2, Version: 1

CoManufacturers and Cofillers Audit

Audit Date:	**July 25 - 27, 2022**
Site Name:	creative werks - Bensenville, Brummel, and Bartlett, IL
Site Manager:	Doug Mauger, VP Operations & Engineering (for all 3 sites)
Quality Manager:	Erich Zicher, Director of Food Safety
Other Site Representatives:	Angela Knabe, Matt Burke, Luis (Maint), Jamas Pugh, Silvana Perez, Martin Garcia, Javier Flores, Dider Mijangos, Scott Nelson, Tony Grandinetti, Brian Phillips
Nestle Audit Team Members:	Donna Bjurlin, Susan Edmondson
Report Sent To:	Angela Knabe, Erich Zicher, Susan Edmondson

Contact Information

Facility Type:	Cofiller	
Address:	1) 222 Sivert Court, Bensenville, IL 2) 1470 Brummel Avenue, Elk Grove Village, IL 3) 1350 Munger Road, Bartlett, IL 60103	
Phone:	(630) 509-3087 - Erich Zicher	
Facility Size / Age:	Bensenville - built in 1977, occupied 1999 Brummel - built in 1977, occupied 2013 Bartlett - built 2006, occupied 2015	Bensenville - ~187,000 sq. ft. Brummel - ~242,000 sq. ft. Bartlett - ~400,000 sf ft
Number of Employees:	~ 237 employees, with 300 - 1500 temporary employees, depending on seasonality	
Number of Production Lines:	Bensenville - 21 Brummel - 16 Bartlett - 28, not including winding (6) & blow molding (6)	
GFSI 3rd Party Certification / Current Rating:	SQF Food Safety Code for Manufacturing & SQF Quality Code	96 Excellent (FS) Certified (Quality)
FDA Registration # / USDA Registration #:	Last 4 digits: BEN - 1646 BRU - 6638 BAR - 0478	N/A
Nestle Business/Category(ies):	Bakery Sweets	

Products Manufactured for Nestle

Co-filling of Morsels (currently Milk & Funfetti), Morsels & More (multiple flavors), Truffles (multiple flavors)

Additional Scope / Background Information

Currently no Nestlé volume in the Bartlett factory, however the site was included in the audit to allow site to continue to be an option.

Overall Audit Rating

Satisfactory/Approved

Executive Summary

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
HACCP	All Nestlé products and their components, including raw materials, packaging materials and process aids, are considered in a HACCP study. All processing steps and movement are considered in the HACCP study.	The Ingredient Risk Assessment document lists potential hazards for high-level ingredient/WIP groups (e.g. chocolate with inclusions, chocolate, or nuts) however no risk assessment (evaluating severity / likelihood) is performed. Risk Assessment documented conclusion (See Auditor Notes) does not negate the site's responsibility to evaluate the risks of the site's incoming materials. The current grouping of ingredients will not adequately support a proper risk assessment of incoming materials Same finding for packaging and process.	Major	One Food Safety Plan for packaging (across all three factories), one for coffee, one for Tubes and Toppers Documented conclusion reached on ingredient hazards in the Ingredient Risk Assessment states, "Client... have instituted policies around Biological and Chemical concerns with their food manufacturers which we verify through our Auto hold / CofA process"	1	Food safety plans will be re-written to included severity and likelihood. Food safety plans will be re-drafted to include the hazard analysis within - not as a separate document. Packaging and process will also be included.	Angie	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
HACCP	An annual review of the HACCP study must take place and all updates must be captured.	Ingredient Risk Assessment changes are not included in the annual reviewed and no change control associated	Major	11/4/21 Pkg Food Safety Plan	2	Since the risk assessment will be embedded within the food safety plan, it will become part of the annual review. New change control froms will include a review of the food safety plan for new processes or products.	Angie	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
Microbiology	The relevant pathogen(s) as well as the associated hygiene indicator(s) has been identified.	Relevant [redacted] tested (e.[redacted])	Minor	Target organisms are Listeria spp and Salmonella; Currently uses hygiene indicators only to show effectiveness of cleaning (validations)	3	Will review the program and how best to address	Erich	31-Mar-23		

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Microbiology	The site Hygienic Zoning program was developed using a risk based analysis.	Sanitation Rooms miscategorized as BGMPs in some documents	Minor	Facility Zoning & Workflow WI-3.1 v10 - dated 2022-01-31 splits facility into 3 zones (non-mfg, BGMPs (all GMPs/partial attire), and PPCA (all GMPs/attire)) Developed based on risk - production environments and the traffic flows around that; Certain areas forktrucks are not allowed due to allergen risks, for example BEN uses Sterliex for forktruck wheels	4	Identifying colors will need to be updated to correctly reflect the zoning.	Angie	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence
Microbiology	The site zoning plan must be supported by verification plan with defined verification activities.	The site zoning plan does not appear to be supported by verification plan with defined verification activities. (WI 3.1 also requires annual verification)	Minor	Facility Zoning & Workflow WI-3.1 v10 - dated 2022-01-31 requires Annual Verification in conjunction with the Pkg FS Plan review	5	WI does require annual verification - will need to update to define what those verification activities are .	Angie/Erich	18-Apr-23	Closed	Brittany Pace - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
[redacted] nt	A MAD form or equivalent local [redacted] raw materials and finished products.	A sample review of the Nestlé Finished Product MAD forms (when compared against the site's ERP [redacted] some MAD forms are incorrect. (e.g. [redacted] pack configurations) Nestlé gap: MAD form for incoming material (NTH White Morsel) is out of date)	Minor	MAD forms exist for all active finished good SKUs (confirmed updated within last 3 years) MAD for [redacted] dicates treenut as allergen in product (highly refined coconut) - but not in ERP setup / labeled on packaging (suspect error) (also not listed in the different ingredients' MAD) NTH White morsel MAD is out of date (Bloomington source)	6	•M&M Peppermint Hot Cocoa – bag has allergens listed as milk & soy, however MAD form dated 3/30/21 (attached) indicates treenut allergen coming from highly refined coconut oil. [redacted] MAD form for accuracy and advise if update is needed / where coconut oil comes from •NTH Premier White Morsel (ingredient) – MAD and Kosher documentation are from obsolete supplier site (Nestle Bloomington) oSusan (by 9/16) – get updated documentation from current supplier site (Nestle Burlington)	[redacted] CW CW Susan	[redacted] 10/1 10/1 11/1	Closed	D. [redacted] Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Allergen Management	Is there an Allergen matrix in place	[redacted] clarity to all involved which lines may run which allergens (based on cleaning [redacted] Currently if a change to a line is made, only quality is aware and it on the Quality personnel to attend every Scheduling meetings to prevent Scheduling from selecting a line that is not current on cleaning validations/verifications or allowed to run that allergen at the moment. (See Auditor Notes for additional context)	Major	Changeover matrix available that specifies all allergens from/to and sanitation requirements. Not product specific info. ERP setups specify the full allergen profile of each item being running. Reviewed SPC1 Line Clearance & Full sanitation Cleaning Checklist after completing NTH Kitchen Sink product (dairy/soy/wheat) to soy/wheat product from Apr'22. Allergen cleaning - full was completed and verified. There is a software that runs a report showing the allergens ran on a line based on the timeline entered. On the line (Ln 380) reviewed, we found that if we looked back to 2021, peanut was listed and when we selected today's date, it is not listed. The line is past due for allergen cleaning verifications. It was stated that they are not allowed to run peanut on the line currently, however when the QAM asked Scheduling of this	7	Matrix will be developed detailing which allergens/clients are approved to run on each of the production lines	Angie	12/31/2022 - realizing this timeline does not meet the deadline for a Major - however, this will restructure how we plan and execute production. More time will be required.	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Allergen Management	Are annual verifications in place?	(Repeat finding) Bensenville could not produce evidence of annual verifications on Ln 380 (and there is no control method to prevent scheduling from running peanut on the line as mentioned above)	Major	BRU - Allergen annual verification on Ln1300 performed 4/18/22, Ln 2400 performed 5/2/22; BEN - the evidence could not initially be located and the QA personnel were on vacation - evidence was found for Ln 200 - 3/31/22; Ln 250 - 8/6 & 8/20/21; Ln 380 - 5/21/21 was the last one performed; See above auditor notes for more context	8	Will audit to determine why we are behind in validations at Ben. Michaela to propose action plan based on schedule.	Angie/Michaela	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence
FM Control	• Equipment under repair/re-construction/maintenance must be inspected, relating to FB, before being cleared for release.	No evidence could be provided to demonstrate equipment under repair/re-construction/maintenance is inspected (relating to FB or micro) before being cleared for release	Minor	assessing as minor due no processing equipment, the # of FM complaints received, and the overall condition of the facility	9	Need to meet with Maintenance and Sanitation to understand the worfklow for items needing maintenance and how those items are then cleared for use in production.	Brian Phillips/Michael Glowa/Angie	1-Jan-23	Closed	D. Bjurlin - Review of submitted evidence
FM Control	Temporary repairs using inappropriate auxiliary materials such as tape, must be avoided. If temporary repairs are used, there must be a policy which includes finite period of time allowed with proper repair scheduled.	There is no mention of an allowed period of time for proper repairs to be scheduled for temporary repairs.	Minor	Generally not allowed unless waiting on a part, etc, however this was a verbal expectation	10	WI for temporary repairs will be updated with the time and materials allowed for temporary repairs	Angie	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Raw, Pack & Finished Prod	Materials received from unapproved vendors trigger the exception management process and documented	In general, approving release for incoming materials from unapproved vendors currently does not include involving Nestlé. Additionally, during a spot check, an example of (Funfetti) film on auto hold was found to come from [redacted] however, the approved supplier (in Ch 5) is Story City, IA. It did not trigger the ER process and was released internally. (We didn't continue to spot check)	Minor	Since it is the Ship From site that triggers the ERP system to auto-hold, it takes extra manual confirmation by Angie to review if the receipt is from a truly unapproved vendor site or not; We reviewed some examples; Typically the issue is the ship from site is a warehouse, and we can see on the paperwork that the manufacturing location is truly the approved site; We aligned that if this wasn't the case, an ER submitted to Nestle would be required for release moving forward. Is there a strong enough tie between the Approved Supplier list in Chapter 5 and the Supplier approval process at CW?	11	Approved cw vendors for Nestle will be verified against the list of approved vendors in Chapter 5. If the shipping paperwork identifies a location other than what is on the approved list, an ER will be submitted to Nestle.	Angie	31-Mar-23	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Raw, Pack & Finished Prod	Information to support the release decision such as sampling, inspection and analytical data must be recorded and traceable by factories.	Incoming receipt COA review is not consistently requiring the full list of required parameters per the Ch 5 specification or the COA comparison table, when available). Example: 6/2/22 Dulce de Leche truffle receipt COA was missing 3 of the 6 micro parameters listed in the spec (included: Eb, S, TPC; missing: YAM, coliforms, and E.coli) (no further spot check performed) The check of the Seal # matching the BOL is not documented.	Major		12	Will review chapter to 5 to determine the micro parameters and then follow up with our suppliers to ensure they are conducting the required tests. Any push back from the suppliers will be escalated to Nestle Quality	Angie	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
Raw, Pack & Finished Prod	The factory is responsible for identifying the release characteristics through the Factory QMS or equivalent. They correspond to: a. Critical Control Points (CCP); b. Operational Pre-Requisite Programs (OPRP); c. Control Points (CP); d. Monitoring inspections (M1) covering contaminants & regulatory requirements (not measured on each batch).	The site's release characteristics are not 100% aligned with the pQMS and/or MI's (Manufacturing Instructions) listed in Chapter 5 (ex: M&M pQMS with regard of level of criticality)	Major	Qwerks is where release characteristics are listed; The FSP is where the SPC and PCPs are denoted	13	Need to review the pQMS to ensure they align with the information contained within the MIs. Once that has been confirmed as aligning, the information in the Mis needs to align with the release criteria listed in Qwerks.	Amanda/Matt/Michaela	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Raw, Pack & Finished Prod	The use of rework is defined by Nestle Technical Applications. Rework is traced and accounted for.	(Nestlé Gap) The use of rework is not defined in Chapter 5	Minor	WI 3.10 Rework requires for multi component that they either separate out the individual components and rework or use a separate scale and manage it to where the ratios are still met. Rework has to be done on the same shift, unless the rework is a result of a hold.	14	CAR#14: I recall the gap identified here around re-processing, not full fledged rework where a new batch# is assigned. Can you confirm? (Maybe question is to @Bjurlin,Donna,US-Solon) If that's the case proposed action: •CW team (by 10/1) – advise if rework (with new batch # assigned) is a process @ CW, and of so share •CW team (by 10/1) – share any policies around online re-processing •Susan (by 11/1) – Draft rework & re-processing requirements from Nestle with alignment from TAG for current portfolio.	CW CW Susan	10/1 10/1 11/1	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Raw, Pack & Finished Prod	Release must be done by: a. The Contract Manufacturer according to mutually agreed standards and rules with Nestlé operating companies, or b. Performed by the Nestlé operating companies	Finished product testing / release is not aligned with the criteria listed in the Chapter 5 (examples found: [redacted]ratios OOS from 6/23 and released, missing end of runs checks in general, line clearance documentation review is not part of release process	Major	Unapproved vendor finding will be addressed in the finding above and not-double dipped here (Line clearance review done earlier in process by other personnel, however there should be some connection that the paperwork is available and complete.	15	Will need to review QMS release parameters with the Food Safety and Quality Managers for each site. Will need to determine if another review of the line clearance sheet needs to be apart of the release process.	Quality Management	1-Nov-22	Closed	D. Bjurlin - Review of submitted evidence
Net Contents	Product intended for US only: 50% or more of individual packages must be greater than declared label net contents (E) as statistically calculated	The Net Content Compliance WI WI-2.18 does not align with this requirement. The WI states "no more than 30% of the actual samples can fall between Label and MAV" Mathematically, this does not guarantee 50% statistically calculated.	Minor		16	Review of Net Contents WI and practices to ensure the mean value of the population is greater than the declared label weight. Adjustments to WI will be made based upon assessment.	Marcus Willamson	1-Feb-23	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Net Contents	Product intended for US only: With Checkweigher, no packed units below an absolute lower limit - No packed units below an absolute limit (MAV). Note (not auditable): Refer to US tab in R3.16.3 Lot Review Selectable Limits USDA MAV Table 2-9 FDA labelled by weight MAV Table 2-5 FDA labeled by count Table 2-7 FDA labeled by liquid or dry volume table 2-6	Found evidence of a production run with MAVs that was being released by site. (Found hold product due to MAVs during factory walkthrough. Internal notes stated "Pallet would be released as the entire lot met spec". No one from Nestle had been informed - M&M, Production date - 7/20/22)	Minor	MAV samples created and ran across checkweigher bihourly 3 times;	17	If finished good failed to meet MAV, this would follow an escalation and ER process which would include Donna to align on next steps.	Matt/Michaela	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence
Net Contents	Product intended for US only: The tare is determined at the beginning of every production is recorded and used for all scale tares.	Tare is not recorded. Tare Variability Study for all products could not be produced per the Net Content Compliance WI WI-2.18, section 5.3.1	Minor	Spot check: the Morsels & More Tare Variability study could not be located	18	Will audit current cw projects running for Nestle to ensure a tare variability study has been conducted and is on file	Matt/Michaela	15-Feb-23	Closed	D. Bjurlin - Review of submitted evidence
Recall & Withdrawal	An after-action review must be conducted when the crisis is over and potential improvements implemented. As a minimum, an analysis of the involved quantities of finished products must be made (produced, sold, returned, destroyed and not accounted for or consumed).	After action review not conducted	Minor	Analysis of quantities accounted for	19	Results of any mock trace or mock recall will be included in the next month's Food Safety team meeting.	Angie	13-Sep-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Non Conform & Change Mgmt	Assess if the deviation leads to material rejection (or if the blocked batches may be exceptionally released or unblocked). Release decision is owned by Nestle Quality.	Release decision for non-conformities is not consistently being brought to Nestlé Quality to own	Major	Discovered two situations where product was held and released by Creative Werks in July without communication to Nestlé. Both were for net content. Other spot check - reviewed peanuts that just went on expiry and were on hold pending review	20	Any Nestle product that is put on hold will be communicated to Nestle Quality to align with disposition. Training from Matt and Michaela to follow.	Matt/Michaela	26-Sep-22	Closed	D. Bjurlin - Review of submitted evidence
Non Conform & Change Mgmt	Check if the same material and/or material batch is (or has been) used in other products and assess the impact accordingly.	Checking to see if the same material and/or material batch is (or has been) used in other products when there is a hold is not documented in the procedure.	Minor	Trace - would run a raw material report to review where used. If any product produced with sublot - automatically put on hold, but if shipped out already - would notify customers. All additional inventory would go on hold.	21	Will update procedure to clearly identify what happens then material from a certain lot goes on hold.	Angie	1-Dec-22	Closed	D. Bjurlin - Review of submitted evidence
Non Conform & Change Mgmt	Each result which is out of the Factory QMS or equivalent limit(s) for a release characteristic must trigger a Root Cause Analysis (RCA) investigation that leads to corrective action(s) avoiding the re-occurrence of the failed result.	Could not provide evidence of consistent root cause / corrective action on all Nestlé product holds consistent with WI and this Nestlé requirement.	Minor	WI-2.7 Corrective Action / Preventative Actions (CAPA) Rev 7, dated 4/17/20 Verbal answer - Per client request will conduct RCA & CAPA. Have internal CAPAs based on trending gap data. No recent CAPAs completed on Nestle items. WI is more black/white on when it is needed vs per client request	22	As part of communicating with Nestle on all holds to align on dispositon, it should be communicated whether Nestle will reuqire an RCA and CAPA on the specific hold.	Matt/Michaela	26-Sep-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
Non Conform & Change Mgmt	The Contract Manufacturer must have a Management of Change process in place to manage changes to products, processes, equipment & workplaces that affect HACCP program, product quality, food safety, regulatory compliance, (e.g.: change on the label).	Insufficient/ineffective MOC process in place. Site could not provide evidence of MOC execution for internally-initiated changes, nor could show proper execution of client-initiated changes.	Major	Examples: M&M ingredient extension MOC dated 1/3/22 NTH Generic Release Instructions 6/29/22, Change in graphics/item formulation gets communicated from client services email and triggers a review. Would get reviewed due to the primary packaging review to assess any allergen updates needed based on change; Unclear how this ties into the change control process. Ingredients - reviewed a FST meeting minutes 7/13/22 where it showed a list of new materials	23	Management of Change program will be rewritten to include a new change control form.	Erich/Angie	3-Mar-23	Closed	D. Bjurlin - Review of submitted evidence
Pest Management	Nestle approved pesticide list is available and communicated to the Site IPM Champions and to the pest contractors	No letter of conformance available from [redacted] acknowledging receipt and adherence to the Nestlé approved Pesticide list	Minor	CW team has shared the current approved pesticide list with Rentokill for review, but verification has not yet been completed. List of Rentokill pesticides used is available in portal	24	Need to confirm Rentokil has uploaded the most current version of the APL.	Angie	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP	A preventative maintenance program is in place for all process equipment that includes record-keeping and verification that work is completed. Maintenance request which impact Product Safety are given priority and on a timeline.	It was not evident during the audit that that Maintenance requests that impact Product Safety are given priority and on a timeline.	Minor	PMs are created when equipment comes in the building; PMs are assigned in ManagerPlus (M Plus); Oldest overdue is from 7/2/22, so appears the sites are staying up on PMs well overall; Run PM completion report weekly; Maintenance work requests are prioritized based on the priority of the line at the time;	25	Severity of repair has been identified in a Departmental Practice for the maintenance departments. Will need to update document to include an appropriate timeframe for each of the categories (Minor, Normal, Major, Critical)	Brian Phillips	1-Feb-23	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP	Following major maintenance, work areas are inspected and released for production, with sign-off by the individuals responsible for the inspection.	At the time of the audit, the site could not provide evidence that following major maintenance, work areas are inspected and released for production, with sign-off by the individuals responsible for the inspection (neither in the way of written (or unwritten) procedure nor documented evidence)	Minor	In the workorder system, the maintenance staff will denote a food contact surface was handled and that will send an email notification to QA; It is unclear what happens after the receipt of that email, even by QA; The work order does not have a check box to denote the line has been released back to production. assessing as minor due no processing equipment, the # of FM complaints received, and the overall condition of the facility	26	Need to meet with Maintenance and Sanitation to understand the worfklow for items needing maintenance and how those items are then cleared for use in production.	Brian Phillips/Michael Glowa/Angie	1-Jan-23	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN & BAR - Warehouse	REPEAT FINDING: Insufficient programs in place to ensure dock doors and the use of said dock doors do not pose quality / food safety risks. Examples: BAR: 9+ dock door seals (drop curtains, wear pleats, etc) are in disrepair BEN - Door 11 had a missing window and the leveler was broken; Door 8 was missing dock leveler brushes; Door 7 leveler brushes deteriorated; Door 10 was left open 2 inches; BRU - Door 6 & others nearby - water ingress when raining; Evidence of air gaps observed in some cases when trailers are backed to the door (These were originally marked as BEN, however realized error and corrected on 2023-01-06)	Major	BAR Dock doors 23 (repeat), 28, 51 (repeat) None of these doors were being used at the time, therefore estimating risk/impact; Two of the three at BAR are repeat findings from last year Many doors were in use and did not allocate resource to evaluate each door at the time of the audit, and as such, there may be additional doors needing attention - suggest comprehensive assessment be performed BRU Warehouse overall looked great and showed nice improvement from last year. Nice work Scott and team! New or updated procedures, training, auditing, and trending required with appropriate management commitment required to address these findings successfully When implement updates	27	Monthly audits and proposed action with timeline will be reviewed and approved through senior leadership.	Warehouse management	17-Mar-23	Closed	D. Bjurlin - Review of submitted evidence
GMP Inspection	BEN - Warehouse	BEN - poor housekeeping especially around dock doors, inside and out, inclusive of excess wood splinters, trash on ground, and items stored in inappropriate locations	Minor		28	Housekeeping schedules will need to be reviewed to ensure areas are free of trash, debris, and wood splinters.	Tony Grandinetti	1-Jan-23	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN - Maintenance Shop	REPEAT FINDING (from sister site): FOB risks are not adequately managed / mitigated in BEN Maintenance shop and tracked to entrance of shop Examples: Metal shavings, bolts, nuts, etc found in multiple areas of the floor and cleaning broom FILLED with shavings; No vacuum near appropriate points of use;	Major	BAR Maintenance shop showed significant improvement, had vacuum near the source of contamination, floor was overall clean, chemicals locked, etc. Luis joined us for the tour (2nd shift) and was very engaged and appreciative of any feedback provided. Good work. BRU Maintenance shop processes still considered Best Practice (Nice work Dave and team); Two associates joined us and clearly articulated their procedures to clean immediately after their work and before going out on the floor, inclusive of their uniforms	29	Ben Maintenance will develop an action plan to ensure FOB are not able to leave the maintenance area. Weekly audit of the area to ensure action plan is working.	Jose Lopez	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN	On Ln250, scale door seals cracked and not appropriately attached to the door, creating potential FOB and micro risks	Major		30	Maintenance manager will review LN250 and submit his recommendation for needed repairs.	Jose Lopez	15-Sep-22	Closed	D. Bjurlin - Review of submitted evidence (Upon review, the gap was really with Ln 200)

SECTION	REQUIREMENT	AUDITOR FINDINGS	RATING	AUDITOR NOTES	CAR #	CORRECTIVE ACTIONS	PERSON RESPONSIBLE	ESTIMATED DATE *(See Comment)*	STATUS	CONFIRMED BY WHO, WHAT
GMP Inspection	BEN	The method used to cover clean equipment is creating foreign body risks (2 or more pieces of clear plastic torn off of the plastic used to cover equipment after cleaning was found on the scale mezzanine and the steps to the mezzanine.	Major		31	Sanitation will review process for covering and uncovering equipment to determine if a different material or process is needed.	Michael Glowa	1-Oct-22	Closed	D. Bjurlin - Review of submitted evidence (Upon review, the gap was really with Ln 200)

UNITED STATES DISTRICT COURT
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Exhibit 8

creative werks

REGULATORY BUSINESS PROBLEM

October 20, 2022

ABSTRACT

Creative Werks LLC's non-compliance to the relevant statutes, standards and regulations under FSMA is an inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders.

Mary Madison
Quality Regulatory Manager

Summary of Problem Statement

Creative Werks LLC's non-compliance with the relevant statutes, standards and regulations under FSMA is an inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders. More specifically for Creative Werks LLC, this non-compliance creates legal liability and culpability due to our breach of contract, breach of fiduciary duty and falsifying documents, among other things, to our clients, the managing members of Creative Werks LLC, governmental regulatory agencies, the end users and society at large. Civil and criminal remedies are results of such liability and can be comprised of monetary judgements, fines, penalties, sanctions, suspension of operations and incarceration or a combination thereof. Other stakeholders could suffer injury, illness or death; in addition, others can suffer loss of employment and economic instability.

Problem Statement

Analysis of the current Food Safety Plans at Creative Werks LLC., evidences that Creative Werks LLC., has year over year, consistently been out of regulatory compliance with the Federal Food, Drug, and Cosmetic Act "hereinafter" (FD&C Act), as amended by the Food Safety Modernization Act "hereinafter" FSMA and its relevant subparts.

Further analysis suggests that there is no cognitive recognition that the Food Safety Plans are out of legal compliance with FSMA. *(See Exhibit A)* Nor is it readily apparent that the lack of compliance is a causal connection to outstanding audit/compliance issues with current customers. *(See Exhibit B*) Also, it can be reasonably inferred that there is a high probability factor that our non-compliance is a root cause in lost business opportunities, such as Pepsi. Further, there is no evidence that a formidable plan of action is in place or being developed to remediate the noncompliance and outstanding compliance issues. *(Exhibit C)*

Moreover, analysis suggests that there has been a failure to apply the relevant statutes, standards and regulations. Additionally, there has been an improper interpretation, analysis and application of the relevant statutes, standards and regulations relative to the business unit's objectives of manufacturing, co-packing and compliance.

Stakeholders

One hundred percent (100%) of our client, customer and vendor base is subject to the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

One hundred percent (100%) of the end users are protected by the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

One hundred percent (100%) of our organization is governed by the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

Compliance

Compliance is achieved by adherence to the relevant statutes, standards and regulations under FSMA and other regulatory schemes. Further, compliance is underscored by overlap and continuity of customer requirements and Creative Werks LLC's protocol's, procedures and policies; coupled, with robust communication and risk management plans skewed to the relevant statutes, standards and regulations under FSMA and other regulatory schemes.

Compliance is not achieved through buzzwords or the sole expressed use of Continuous Improvement methodologies and tools. Additionally, quality and compliance are often treated and used interchangeably; however, there is a vital difference between these two terms. Specifically, regulatory compliance is compulsory and must be followed by any business wishing to engage in the stream of commerce.

Non-compliance negatively affects our sustainability, goodwill, and profitability here at Creative Werks LLC. In addition, it creates a public health threat and potential public health crisis.

Risks

A vast range of inherent risks exist that impacts our organization; such as, customer supplied/source suppliers to supplier/vendor performance matrices to allergen control among other risk factors. Risks can either be business or regulatory risks or a combination of both risks thereof. Each risk is to be evaluated cumulatively for maximum optimization, including internal risks. Further, there are risks associated with training, scientific validation and verification, monitoring, documentation, and recordkeeping that must be line balanced for verification of implementation and effectiveness, as required by law.

Ongoing risk management is essential in this ever-changing environment. This proactive stance helps protect our brand reputation and business while creating operational efficiencies. Failure to build mitigation strategies around business and compliance risks identified, forecloses opportunities to improve, avoid complacency and litigation.

Cost of Doing Nothing

Since the inception of the Preventive Controls regulations, Creative Werks LLC has never been compliant and has had repeated violations from numerous customer audits. We also have approximately 139 open document requests from various customers that have been outstanding since 2021 that are inextricably linked to our non-compliance. *(See Exhibit D)* We also have lost business opportunities that translate into the loss of dollars, profitability and goodwill; translating into market share loss. Further, we have noted infractions and/or violations from the FDA for non-compliance that are available for public inspection and review.

Also, a culture that is diametrically opposed to the transparency mantra of Creative Werks LLC has evolved. Further, this culture exhibits and encourages a blatant disregard for the law. Additionally, this

conduct is in direct contravention to domestic and international regulatory framework used for transparency to promote and underscore food protection initiatives.

If we do nothing, we can expect more of these and other scenarios; along with an increase in lost revenue, increased legal exposure and lawsuits among other things.

Further if we do nothing, we will also be in violation of other subparts of FSMA that require us to act swiftly in implementing an immediate course correction among other things. Failure to act swiftly within the prescribed time frame will also subject us to additional civil and criminal liabilities for once again failing to comply with the standards.

Legal Exposure

Legal liability is triggered each and every day that compliance is not achieved. It also occurs on a transactional level on multiple fronts for all stakeholders.

Legal liability is governed by statutes of limitations relative to the claims asserted that are tied to either state or federal laws.

For example, product liability has a two (2) year statute of limitation. The statute of limitation is triggered when the person becomes aware that they have been harmed.

E.g. the incident raised, by the FDA in its September 2022 inspection, relative to product failure in conjunction with Pepsi that was reported in October of 2021. This incident has an expiry date for civil liability of October 2023. Criminal liability has no statute of limitation.

Another example is our current production of Valentine and Easter products the legal exposure is two (2) years beyond an adverse event. i.e. after product distribution and consumption by the end user. This pushes this liability exposure out past Valentine and Easter of 2025.

Further, most recently legal precedent supports that insurance companies reject indemnifying insureds for breach of any fiduciary duty; including non-compliance; thus, leaving us to settle any outstanding judgments at law or debts with company assets.

Recommendations:

Implement an immediate course correction.

Refrain from hiring any persons or purchasing any compliance aids until a needs assessment is conducted and analyzed that supports a formidable plan of action accompanied by a supporting business case.

Implement proper oversight.

Identify, interpret and apply the proper relevant statutes, standards and regulations necessary to achieve compliance.

Line balance the appropriate standards against customer requirements.

Develop, implement and sustain communication plans.

Implement a Risk Management program.

Contract Management

Choose a certification that synergizes all the necessary elements for compliance and success.

Answer questions as asked; speak only to issues at hand.

Refrain from comingling facts from various situations or instances.

Refrain from comingling relevant statutes, standards and regulations during audit and inspection proceedings.

Other Recommendations:

Restructure Creative Werks LLC to a series LLC to reduce liability and exposure. i.e. Have a series LLC for each client or venture. E.g. Creative Werks-PepsiCo LLC

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Exhibit 9

From: Steve Schroeder[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=576157045B2E4CFD8F668B80846D752D-SSCHROEDER@]

Sent: Mon 10/24/2022 8:21:35 PM (UTC)

To: Gretchen LeMay[glemay@cwerksglobal.com]

Subject: Serious Concern

Gretchen,

Per our brief discussion I want to provides some notes around the very disturbing conversation I had with Mary Madison on Friday afternoon after our Company Meeting. As you know I always encourage an open door so when I met Mary earlier in the week I welcomed her to come sit down and tell me a little bit about her background and what brought her to CW. She had told me she was a graduate of Johns Hopkins like me.
When Mary came to my office on Friday she handed me a bound document that had a very threatening statement on the cover and also in the first paragraph that I skimmed briefly. Seemed to have been put together by a lawyer. In our conversation she said that our company does not follow food safety guidelines. I, of course, told her that that was not true and that we always strive to follow the letter of the law and have never once been sited by the FDA or any other government body of violating the law. I told her that we go through many many audits annually by our clients and also third party auditors. She intimated that they also probably do not know what they are doing and that because they give us approvals it does not exonerate us. Of course we have to be responsible.

I asked her if she had spoken to her direct manager about her finding and she said she had not other than when she asked for certain clarification on items in our Food Safety Plan he could not point to research that confirmed some of our statements. She said we receive product and have not done enough analysis on every item. When I challenged her that our clients are shipping us product and certifying that product she said that we cannot rely just on that. We should be doing our own analysis. When I asked her if we should be testing our clients food with third party labs she said no. Not sure what she was expecting of us.

She stated that on her first day of employment at creative werks she participated in an FDA visit regarding a complaint. She stated that Eric provided too much information to the auditor and that he should have only answered her questions in very narrow terms. She seemed very confused about the visit and the timing of the incident that led to the visit. When I told her that we did not receive a 483 citation her only comeback was that I did not know what the FDA person was writing down. I reassured her that we take food safety very seriously and comply with the letter of the law. Not really sure what she was trying to get at.

She brought up a term GRAS (Generally Recognized as Safe) in the Dunkaroos Food Safety Plan that was on page 14 of 36 as it regards the use of x-ray equipment and the potential contamination of food by using this type of equipment. She said that since it is a piece of equipment that must be registered with the State of Illinois we cannot use the term GRAS. She then went into a whole discussion about dentists use of x-ray equipment. I said that this is not similar and that this is a common tool that food companies use to test for foreign materials. She said that she spoke to someone about the x-ray flaps and if they are not taken care of radiation could leak. I asked if that

was an observation when she visited the line in our Bartlett plant and she then told me she has never visited the plant. In our Food Safety Plan we state that all x-rays in our network are serviced and tested annually for leakage. She said well maybe they should be checked more often. I told her to review the requirements of our language and make change it if she believed it was deficient. She said that we could not rely on the x-ray equipment manufacturer to provide a safety statement. We had to find a study or do the research ourselves. I told her to also look at any contamination statement and modify them and more importantly help us with better practices.

About 2 hours into the meeting I just got a strong sense that she had no interest in helping us get better. I had the feeling of some sort of extortion effort going on. She kept on saying well maybe all the information is there somewhere. I asked if she had for instance looked into how we manage x-ray equipment or any statements related to food contamination by the x-ray providers. She said no she had not.

I asked her if she had shared any of her concerns with Eric and she said that she had asked him questions but she did not insinuate that she had. I asked her if she had spoken to Ron Sammeth and she said that she did not know who he was or his role. I reminded her that he was the COO and that he had been the head of Supply Chain for Mars Wrigley a company very tuned into food safety. I reminded her that he had presented at our company meeting that she attended only two hours earlier.

She also brought up that we had one unresolved corrective action from our Nestle audit. When I told her we had until November 1st according to the document she showed me to clear it up she did not have a comeback other than to say well we might not get it resolved.

One other point she brought up is that we should create LLC's for projects to reduce our liability as a business. That was a bit surprising and just something i was sure she heard in a class on how to reduce legal liability. Not the way we operate.

During our company meeting she was introduced as a new hire. When I asked her how long she had been at cw she said 3 weeks. I told her that was not much time to come up with all of the accusations and judge our business in such a harsh way. She did not respond. Seems like she was looking for something other that helping us improve our business.

[[#]]
Name: Steve Schroeder
[[#]]

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Exhibit 10

Exhibit 6

creative werks
1470 Brummel Ave
Elk Grove Village, IL 60007
www.creative-werks.com
630.860.2222

Notice of Suspension

October 26, 2022

Mary Madison
Quality Regulatory Manager
Via Hand Delivery

Dear Mary,

This letter is to inform you that you are being placed on a paid suspension effective immediately. This suspension will last until a full investigation into the statements made in your report and during your conversation with Steve Schroeder on Friday, October 21, 2022 can be fully completed. This review will be conducted by an outside attorney and Human Resources will make the introduction when the time comes.

During your suspension you will be paid at your regular rate of pay and have access to benefits. You will not have access to any IT systems or the building until the investigation is complete.

If you have further questions, please reach out the HR team as needed.

Thank you,

Gretchen LeMay
Head of People